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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Application for:  
Teni BOULIKAS  
Application Serial No.: 09/434,345  
Filing Date: November 5, 1999  
For: **THERAPY FOR HUMAN CANCERS  
USING CISPLATIN AND OTHER DRUGS  
OR GENES ENCAPSULATED INTO  
LIPOSOMES**

Examiner: J. Kerr  
Group Art Unit: 1633  
Attorney's Docket No. 131561-200100

**RESPONSE TO RESTRICTION REQUIREMENT**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

This paper is submitted in response to the Restriction Requirement issued by the U.S. Patent and Trademark Office on March 27, 2001 in connection with the above-identified application. A response to this Action originally was due on April 27, 2001. Applicant submits herewith a petition for a one month extension of time and corresponding fee as a small entity, making this paper due May 29, 2001 (May 27, 2001 being a Sunday and May 28, 2001 being a Holiday). Accordingly, this response is timely filed.

**I. ELECTION OF GROUP/SPECIES**

Applicant elects Group I, with traverse, for further prosecution in the subject application.

## **II. RESPONSE TO RESTRICTION REQUIREMENT**

The Examiner required an election of one group for examination among the following groups:

I. Claims 1-19, drawn to a method of producing cisplatin micelles, methods of using the cisplatin micelles, and the cisplatin micelles, and classified in class 424, subclasses 450 and 649, for example.

II. Claims 24-26, drawn to a method of inhibiting tumor growth in a subject by administering a transgene, classified in class 414, subclasses 450 and 649, and class 514, subclass 44, for example.

III. Claim 27, drawn to a composition comprising cisplatin micelles and oligonucleotides, ribozymes, triplex, or PNA, classified in class 414, subclasses 450 and 649, and class 514, subclass 44, for example.

IV. Claim 28, drawn to a composition comprising cisplatin micelles in combination with drugs, classified in class 424, subclasses 450 and 649, and class 514, subclasses 675 and 724, for example.

Applicant's attorney hereby affirms this election, with traverse, to prosecute the invention of Group I (claims 1-19). However, Applicant expressly reserves his right under 35 U.S.C. § 121 to file one or more divisional applications directed to the nonelected subject matter during the pendency of this application, or an application claiming the benefit of this application under 35 U.S.C. § 120.

Applicant respectfully requests reconsideration and withdrawal of the requirement for restriction among Groups I and II (claims 1 to 24 inclusive).

There are two criteria for a proper requirement for restrictions, namely, (1) the inventions must be independent or distinct, and (2) there must be a serious burden on the Examiner if restriction is not required. Under MPEP § 808, the Examiner must examine the subject application on the merits even though it includes claims two distinct inventions, if the search and

examination of the application can be made without serious burden. In the instant application, the claims drawn to the method of claims 24 to 26 (Group II) utilize the micelles produced by the claims of Group I (claims 1 and 10). Therefore, a search of the art for references related to the subject matter of the claims of Group I may likely uncover references related to the subject matter of Group II.

Accordingly, in view of the preceding discussion, Applicant respectfully asserts that two or more independent and distinct inventions have not been claimed in the subject application between the inventions of Group I and II, as the groups are not independent under MPEP § 802.01. Therefore, restriction is not proper under 35 U.S.C. § 121.

In view of the preceding remarks, Applicant also maintains that the allegedly distinct inventions of Groups I and I are not distinct because the claims of Group II are dependent upon the claims of Group I and therefore cannot be practiced without practicing the invention of Group I. Therefore, under MPEP § 803, a restriction requirement is not proper between Groups I and II and the requirement for restrictions should be withdrawn.

The Office also requested an election of species for the elected claims. For each claim falling within an elected Group, i.e., claims 3, 5, 11 13 and 24 of Groups I and II, Applicant elects the species recited in subgroup (a).

### III. CONCLUSION

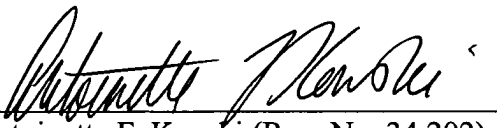
If a telephone interview would advance prosecution of the subject application, the Examiner is invited to telephone the undersigned at the number provided below.

In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0974**, referencing attorney docket no. **131561-200100**.

However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Date: May 8, 2001

By:   
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